MAR 0 6 2014

5 510(k) Summary

Contact:	Michelle McDonough Musculoskeletal Clinical & Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 202.552.5800
Date Prepared:	March 6, 2014
Device Trade Name:	N-Force Fixation System
Manufacturer:	InnoVision, Inc. 1975 Nonconnah Boulevard Memphis, TN 38132
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification:	21 CFR 888.3040
Class:	II
Product Code:	HWC

Reason for Special 510(k) Submission:
The purpose of this Special 510(k) is to add new sizes and components to the N-Force Fixation System. There have been no changes to the intended use of the device or its fundamental scientific technology.

Indications For Use:
The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver the following bone void fillers to a surgical site:

- Beta-bsm (ETEX Corporation)
- CarriGen (ETEX Corporation)

Device Description:
The N-Force Fixation System is a screw system for fracture fixation. It includes fully and partially cannulated screws in various diameters and lengths, and accompanying instruments.

The N-Force Fixation System implants are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The N-Force Fixation System screws are cannulated and/or

fenestrated and can be used as a delivery system for ETEX Beta-bsm and ETEX CarriGen bone void fillers.

Predicate Device:
The modified N-Force Fixation System is substantially equivalent to the predicate N-Force Fixation System (K102528) with respect to indications, design, function, performance and materials.

Substantial Equivalence:
Testing was performed on the modified N-Force Screw compared to the predicate N-Force Screw, and the results demonstrate that it is substantially equivalent to the predicate device. Mechanical testing of the modified screw included static three-point bending, static torsion and extraction testing. Engineering analyses were also provided in support of the non-fenestrated screws' substantial equivalence. Additional testing was performed to demonstrate the substantial equivalence of the N-Force Fixation System to the ETEX recommended instruments with respect to their ability to deliver bone void filler material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

InnoVision, Inc.
% Ms. Michelle McDonough
Senior Associate, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC
1331 H Street NW 12th Floor
Washington, District of Columbia 20005

Re: K132244
Trade/Device Name: N-Force Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 5, 2014
Received: February 6, 2014

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number (if known): K132244

Device Name: N-Force Fixation System

The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver the following bone void fillers to a surgical site:

- Beta-bsm (ETEX Corporation)
- CarriGen (ETEX Corporation)

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices